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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,514	09/22/2003	Marius Hauri	0100/0165	5820

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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/665,514

Applicant(s)

HAURI ET AL.

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,13-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-5, 8-11, 13-21, 23-24, 27-28 is/are rejected.
- 7) ☒ Claim(s) 6,7,25 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/14/06
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/06 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, 9, 20-21, 23, & 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Crawford et al (US Pub. No. 2002/0161336A1). The Crawford reference discloses a safety apparatus in figures 1-14 comprising a needle hub 60 having a proximal portion and a distal portion, a needle 40 extending from a distal end of said needle hub; a collar 90 rotatably mounted directly on the distal portion of said needle

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hub, said collar having a first engage mechanism 97 at its inner circumferential surface; a housing 140 pivotally connected to said collar; and a needle sheath 50 having a proximal portion with a second engage mechanism 56 at its outer circumferential surface, said first and second engage mechanism fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said needle hub when said sheath is fitted to said collar and said first and second engage mechanism are engaged to each other.

With respect to claims 2 & 21, see figure 12.

With respect to claims 4 & 23, wherein second engage mechanism 56 comprises a groove and first engage mechanism 97 comprises a rib, see figures 2, 9, & 10.

With respect to claims 9 & 28, wherein the collar has a lock mechanism 118 and wherein the housing has an other lock mechanism 194 for coacting to fixedly retain the housing.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further

in view of Landis (US Patent No. 5490841). The Crawford reference discloses the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Crawford in order to easily entrap the needle with the housing.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Gyure (US Patent No. 5669889). The Crawford reference discloses the claimed invention except for lock mechanisms on the collar and housing utilizing an aperture. The Gyure reference teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61,57, figure 3). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure in the apparatus of Crawford in order to provide a lock mechanism for one-way safety locking to prevent re-exposure of the needle after covering.

Claims 5 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Johnson (US Pub. No. 2002/0010433). The Crawford reference discloses the claimed invention except for a ring spaced around the hub end for a user to grasp. The Johnson reference teaches a ring spaced around a hub end for a user to grasp (figures 2a-e). Therefore it would be obvious to one of ordinary skill in the art at the time of the

invention to use the teachings of Johnson in the apparatus and method of Crawford in order to facilitate connection of the hub and barrel.

Claims 11, 13 & 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US Pub. No. 2002/0010433) in view of Gyure (US Patent No. 5681295) and Lockhart (US Patent No. 2693183). Johnson discloses a needle hub having a luer connection 68 at a proximal portion, and a ring 42 graspable by a user to remove the needle hub from a syringe surrounding, in spaced relation, to the luer connector (figures 2A-F). Johnson does not disclose a window provided at the hub ring, a collar having a pivotally connected housing rotatable about the hub, first and second engagement mechanisms. Gyure best shows the sheath 337, hub 328, and collar 341 arrangement in figure 12. Though Gyure states that the base is a separate piece assembled to the hub in an interference fit (like the interference fit of the collar to the hub) (col. 9, line 42 – col. 10, line 34), the prior art discloses that the base 330/30. The sheath has an engagement mechanism (proximal portion of the sheath fit into the collar in figure 12) and the collar has an engagement portion (distal portion in contact with the sheath). In the same way the collar is not considered a part of the hub, the base can also be considered not a part of the hub. In one view the sheath 337 is attached only to the collar because the base 330 and element 341 are considered element of the collar. Gyure further teaches a collar having a pivotally connected housing rotatable about the hub (Figure 12) to position a needle guard adjacent a needle that can cover the needle to protect against accidental punctures.

Furthermore, claim 11 does not require the limitation of attaching a sheath only to a collar. In this regard Gyure '295 discloses a safety apparatus including a needle hub, collar rotatably mounted, housing pivotally connected to the collar, needle sheath 37, engage mechanism (40 and proximal portion, hub distal portion) on the sheath and collar respectively, needle hub with flange and wall 33, 32, and collar protrusion 43 as recited in claim 17. See figure 2.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '295 in the safety apparatus of Johnson in order to lower the risk of accidental punctures with syringe needle by shielding the needle. Lockhart teaches a window at a needle hub to allow visual access to the interior of the hub. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Lockhart in the safety apparatus of Johnson and Gyure '295 in order to see if blood was present on the interior surface of the hub that could contaminate surfaces during or after use of the needle hub.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson, Gyure '295, and Lockhart as applied to claim 11 and further in view of Crawford (US Pub. No. 2002/0161336a1). Johnson, Gyure'295, and Lockhard disclose the claimed invention except for a groove on the needle sheath to mate with a circumferential rib on the collar inner wall. Crawford teaches a groove and rib combination to secure a sheath to a collar. See Figure 2, 97 on collar and groove between elements 56 on sheath 50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Crawford in the apparatus

and invention of Johnson, Gyure '295, and Lockhart in order to provide a secure fit between the sheath and collar.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson, Gyure '295, and Lockhart as applied to claim 11 and further in view of Landis. Johnson, Gyure '295, and Lockhart disclose the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Johnson, Gyure '295, and Lockhart in order to easily entrap the needle with the housing.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson, Gyure '295, and Lockhart as applied to claim 11 and further in view of Gyure (US Patent No. 5669889). Johnson, Gyure '295, and Lockhart disclose the claimed invention except for lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar. Gyure '889 teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61, 57, figure 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '889 in the apparatus and method of Johnson, Gyure '295, and Lockhart in order to prevent the housing from re-exposing the needle after covering.



***Allowable Subject Matter***

Claims 6-7 & 25-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments with respect to claims 1-2, 4-10, 20-21, 23-28 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claim 11 and its dependents filed 6/22/06 have been fully considered but they are not persuasive. Applicant claims that the amended independent claim overcomes the prior art with respect to claim 11 and its dependents, the examiner disagrees. The reference still discloses the ring 42 to be graspable by a user to remove said needle hub from the syringe.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*